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10/594,436

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Takashi Yoshitake

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EXAMINER

ORWIG, KEVIN S

ART UNIT

PAPER NUMBER

1611

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,436	<b>Applicant(s)</b> YOSHITAKE ET AL.	
	<b>Examiner</b> Kevin S. Orwig	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 21-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Sep. 26, 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/26/06, 1/17/07, 7/25/07, 10/17/07, 10/31/07, 3/3/08.

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 1-30 are currently pending. Claims 1-24 are the subject of this Office Action. This is the first Office Action on the merits of the claims. Non-elected claims 25-30 are withdrawn from consideration.

### ***Election/Restrictions***

Applicants' election of Group I (claims 1-20) in the reply filed on Jan. 15, 2009 is acknowledged. In response to applicant's election, Group III (claims 25-29) is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Upon further consideration, Group II (claims 21-24) has been included with Group I, and claims 1-24 have been examined further on the merits. Applicants have elected Group I with traverse.

The traversal is on the ground(s) that an examination of all the pending claims would not constitute a serious burden. This traversal is not found to be persuasive because applicants have not shown that the groups of inventions have a general inventive concept under PCT rule 13.1. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features, meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. As set forth in the restriction requirement dated Dec. 15, 2008, applicants'

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special technical feature is a controlled-release pharmaceutical formulation comprising a core with a coating, which is not a contribution over the art as evidenced by at least the combination of Aoki and Nakajima as discussed below. Hence, there is no technical relationship over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features.

Thus, the restriction requirement between Groups I and III is still deemed proper and is therefore made FINAL.

In the response of Jan. 15, 2009, applicants elected the following species:

Water-insoluble polymer: ethyl cellulose

Enteric polymer: methacrylic acid-methyl methacrylate copolymer (i.e. Eudragit)

Hydrophobic wax: magnesium stearate

Benzimidazole-based compound: rabeprazole

### ***Information Disclosure Statement***

References lined-through on the information disclosure statement(s) were not considered because they were not provided or were not provided in English.

### ***Claim Objections***

Claim 22 is objected to because of the following informalities: the word "composition" in the last line of the claim should be "compositions".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112 (2<sup>nd</sup> Paragraph)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.** Claims 21 and 22 recite: A preparation/package comprising 1) the controlled-release pharmaceutical composition according to claim 1 and 2) an enteric pharmaceutical composition in which a core containing an acid-unstable physiologically active substance is covered with an enteric coating. These two elements are duplicative. It is noted that element 1) (i.e. the controlled-release pharmaceutical composition according to claim 1) IS an enteric pharmaceutical composition in which a core containing an acid-unstable physiologically active substance is covered with an enteric coating. Thus, elements 1) and 2) of claims 21 and 22 recite two components having the same limitations and it is unclear what limitations the second element is intended to add to claim. Thus, the metes and bounds of claims 21 and 22 and the claims dependent thereon (i.e. claims 23 and 24) are unclear.

### ***Priority***

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be Mar. 23, 2005, the filing date of PCT application PCT/JP05/05217 to which the instant national stage 371 application claims priority.

Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). It is noted that the certified copy of the Japanese application has **NOT** been received by the USPTO.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over AOKI (WO 03/043661; Published May, 30, 2003; 3<sup>rd</sup> foreign reference on IDS dated**

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**Sep. 26, 2006; the corresponding national phase publication U.S. 2005/0163846, reference CR on IDS dated Jul. 25, 2007 is relied upon as an English language equivalent for the rejection set forth herein) in view of NAKAJIMA (JP 2000128779; Published May 9, 2000; last foreign reference on IDS dated Sep. 26, 2006; machine translation provided).**

1. Aoki discloses sustained- or pulsed-release pharmaceutical preparations in the form of tablets or granules of an acid-unstable compound. These compositions comprise a core containing the acid-unstable compound, which is covered with a coating that contains a mixture of a water-insoluble polymer and an enteric polymer (abstract). The core contains a benzimidazole compound, preferably rabeprazole (elected species) (paragraphs [0024], [0036], [0052]; claim 10) and may contain crospovidone as a preferable disintegrant (paragraphs [0054], [0059], and [0060]). Regarding the coating, discloses embodiments wherein the preferred water-insoluble polymer is ethyl cellulose (elected species) and the enteric polymer is methacrylic acid/methyl methacrylate copolymer (elected species) (paragraph [0020]). Aoki teaches that the coating further contains a plasticizer including, *inter alia*, triethyl citrate, cetyl alcohol, glycerol fatty acid ester, and propylene glycol (paragraphs [0017] and [0021]). Aoki teaches that the coating preferably contains an alkaline substance such as, *inter alia*, sodium and potassium hydroxide (paragraphs [0018] and [0022]). Aoki teaches the use of magnesium stearate (elected species) as a lubricant component of the core but not a component of the coating.



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2. However, the use of magnesium stearate in coatings was known in the art at the time of the invention. For example, Nakajima discloses a pharmaceutical preparation comprising a core that includes a drug and a water-swelling substance (paragraph [0019]; claim 1). This core is coated with a film for controlling the release of the drug. The film may contain ethyl cellulose, an enteric polymer, and a water-insoluble substance (paragraphs [0019], [0020], and [0029]). Nakajima teaches that the time from administration of the medication to initial release of the drug (lag time) can be controlled with good reliability by adjusting the type and amount of the water-insoluble substance contained in the film for controlling the release of the drug (paragraph [0070]; claim 1). The water-insoluble substance may advantageously be magnesium stearate (paragraph [0031]; claim 2). Thus, one of ordinary skill would have been motivated to use magnesium stearate in the coating taught by Aoki to help adjust the lag time of the controlled-release compositions as taught by Nakajima. Claims 1-3, 5-11, and 16-20 are obvious over Aoki and Nakajima.

3. Aoki teaches the use of an inert intermediate coating between the core and the enteric coating to separate the somewhat acidic enteric coating from the core (paragraph [0068]), rendering claim 4 obvious.

4. Regarding claims 12-14, Aoki teaches that the water-insoluble polymer is present in an amount from 20-80%, preferably from 25-75% by weight relative to the weight of the water-insoluble polymer and the enteric polymer (paragraphs [0016] and [0078]) (reading on claim 14). Nakajima teaches the use of the water-insoluble substance from 75-1500 parts by weight relative to 100 parts by weight of ethylcellulose (paragraph

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[0028]; claim 1). Furthermore, Nakajima teaches adjusting the amount of water-insoluble substance in the coating (paragraph [0070]). In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to optimize the amount of water-insoluble substance (i.e. the hydrophobic wax). One would have been motivated to do so to modify the lag time of the controlled-release composition as taught by Nakajima. Thus Aoki and Nakajima render claims 12-14 obvious.

5. Aoki teaches amounts of the plasticizer from 0.5-8% (depending on ethanol content) by weight relative to the total weight of the coating (Example 1), rendering claim 15 obvious.

6. Regarding claim 21, both Aoki and Nakajima teach the formulation of their compositions as capsules (see Aoki, paragraph [0048]; and Nakajima, paragraphs [0022], [0039], and [0040]; claims 6-12).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention

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as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

**Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki (as evidenced by U.S. 2005/0163846) in view of Nakajima as applied to claims 1-21 above, and further in view of WHITTLE (U.S. 6,444,689; Issued Sep. 3, 2002).**

7. The teachings of Aoki and Nakajima are presented *supra*. Aoki and Nakajima are silent to the packaging of their compositions. Nonetheless, one of ordinary skill in the art would have known to package the compositions for convenience and storage as is customary in the art.

8. For example, Whittle discloses pharmaceutical preparations of benzimidazole compounds as enterically coated tablets, capsules, or sachets (col. 44, lines 37-40). Whittle teaches that packaging the final dosage form is desirable for long term stability of the dosage form since a desiccant can be added to the package to reduce the water content of the preparation (col. 44, lines 41-49). Thus, claims 22-24 would be obvious to an ordinary artisan in light of Aoki, Nakajima, and Whittle.

**Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over SAEKI (U.S. 5,035,899; Issued Jul. 30, 1991; Reference AR on IDS dated Oct. 17, 2007) in view of Aoki.**

9. Saeki discloses pharmaceutical preparations, including tablets and capsules, of an acid-unstable compound comprising a core containing the acid-unstable compound,

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which is coated with a hardly water-soluble film forming material, a hardly water-soluble substance, and an enteric film (abstract). The acid-unstable compound is a benzimidazole compound, most preferably rabeprazole (elected species) (abstract; col. 2, lines 16-18; claims 1, 3, and 5). Saeki discloses embodiments wherein the hardly water-soluble film forming material is ethyl cellulose (preferably at least 10%) (elected species) (col. 2, lines 46-48), the hardly water-soluble substance is magnesium stearate (elected species) (col. 2, lines 42-43; claim 1), and the enteric film is methacrylic acid/methyl methacrylate copolymer (elected species) (col. 3, lines 12-15). The water-insoluble polymer is approximately 50% of the total weight of the water-insoluble polymer and the enteric polymer (col. 2, lines 45-48, as well as the examples, wherein Saeki gives weights and teaches the water-insoluble and enteric coatings weigh approximately 10 mg each). Instant Claim 5 is obvious over Saeki because the ability to be used for pulsed-release is inherent to the structure, which is directly taught by Saeki. Saeki teaches an alkaline substance (magnesium oxide) (table in example 1) and a plasticizer (col. 8, lines 14-16). Thus, Saeki discloses each element of the instantly claimed composition except for the inclusion of a disintegrant in the core. However, the use of disintegrants in similar pharmaceutical preparations was well-known at the time of the invention.

10. For example, Aoki discloses preparations that are substantially identical to those instantly claimed (see discussion *supra*). Aoki teaches that the use of disintegrants together with an alkaline substance will contribute to better stabilization of the benzimidazole-based compound. Thus, it would have been *prima facie* obvious to one

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of ordinary skill in the art at the time of the invention to include a disintegrant in the core of Saeki's compositions together with an alkaline additive, to provide a more stable benzimidazole preparation per Aoki's teachings. In combination, Saeki and Aoki render the instant claims obvious.

**Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki (as evidenced by U.S. 2005/0163846) in view of Nakajima as applied to claims 1-21 above, and further in view of CHEN (U.S. 2002/0045184; Published Apr. 18, 2002).**

11. The teachings of Saeki and Aoki are presented *supra*. Saeki and Aoki are silent to the packaging of their compositions. Nonetheless, one of ordinary skill in the art would have known to package the compositions for convenience and storage as is customary in the art.

12. For example, Chen discloses packages for dispensing proton pump inhibitors (abstract). The packaging includes a blister card (i.e. a blister pack), each blister of which may comprise a unit dosage form (e.g. a tablet or capsule) of a proton pump inhibiting drug (paragraphs [0008], [0042]). Chen teaches that the packaging is advantageous for easy distribution and administration (paragraph [0005]). Thus, claims 22-24 would be obvious to an ordinary artisan in light of Saeki, Aoki, and Chen.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re*

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*Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

### U.S. Patent Application No. 11/543,991

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-20 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-20 of copending Application No. 11/543,991. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The two claim sets are identical.

### U.S. Patent No. 10/849,544

Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-8, and 10-12 of copending Application No. 10/849,544 in view of Aoki and Nakajima. Although the conflicting claims are not identical, they are not patentably distinct from each other

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because the scope of the '544 claims renders obvious that of the instant claims. The difference between the two claim sets is that the instant claims recite the inclusion of a disintegrant (claim 1) and an alkaline substance (claim 3) in the pharmaceutical preparation. However, these elements, and thus the entire scope of the instant claims is rendered obvious since, by the reasoning presented in the rejections *supra*, the use of a disintegrant, an alkaline substance, and the instantly claimed weight percentages of all the components are obvious variations based on the prior art.

Claims 1-20 directed to an invention not patentably distinct from claims 1-3, 5-8, and 10-12 of commonly assigned 10/849,544. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/849,544, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon

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the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

U.S. Patent No. 10/938,554

Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41-43, and 45-55 of copending Application No. 10/938,554 in view of Aoki and Nakajima. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '554 claims renders obvious that of the instant claims. The difference between the two claim sets is that the '554 claims recite the inclusion of mannitol and the instant claims recite the inclusion of a disintegrant (claim 1) and an alkaline substance (claim 3) in the pharmaceutical preparation. However, these elements, and thus the entire scope of the instant claims is rendered obvious over the prior art. It is noted that Aoki teaches the use of an inert intermediate coating and teaches mannitol as a suitable inert material. By the reasoning presented in the rejections *supra*, the use of a disintegrant, an alkaline substance, and the instantly claimed weight percentages of all the components are obvious variations based on the prior art.

Claims 1-20 directed to an invention not patentably distinct from claims 41-43, and 45-55 of commonly assigned 10/938,554. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP



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Chapter 2300). Commonly assigned 10/938,554, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

### ***Conclusion***

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/

Primary Examiner, Art Unit 1643